## REMARKS

The applicants have studied the Office Action dated December 15, 2004, and have made amendments to the application. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 1-11 and 21-24 are pending, claims 1, 3 and 21 have been amended, and new claim 24 has been added. Reconsideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

Support for amended claims 1 and 21 can be found generally throughout the specification including paragraphs **[0019]-[0020]**. Support for amended claim 3 and new claim 24 can be found generally throughout the specification including paragraphs **[0022]-[0023]**. No new matter has been added.

Claims 1, 2, 4, 6-8, 21, and 22 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,830,209 to Savage et al. This rejection is respectfully traversed.

Embodiments of the present invention are directed to an implantable sensor system comprising an implantable sensor with a proximal end anchored within the patient. The implantable sensor system further includes a flush sleeve over the length of the sensor and a rinsing fluid delivered through the flush sleeve to spray the sensor tip and remove buildup that can affect sensor measurements. Amended independent claim 1 (and thus dependent claims 2, 4, and 6-8) now recites "[a]n implantable sensor system for taking readings from a patient in vivo, the sensor system comprising: an implantable sensor having a distal end with a sensor tip for direct contact with patient fluids and a proximal end to anchor the implantable sensor within the patient; a flush sleeve directed towards the sensor tip; a rinsing fluid; and a fluid conduit in fluid communication with the flush sleeve, wherein the rinsing fluid received in the fluid conduit is used to spray the sensor tip, and wherein the flush sleeve concentrically surrounds the implantable sensor around a substantially common axis, such that the sensor is within the flush sleeve" (emphasis added). Independent claim 21 (and thus dependent claim 22) recites similar language. The Savage et al. reference does not disclose, teach or suggest an implantable sensor

with a proximal end for anchoring the implantable sensor within the body of the patient and a distal end with a sensor tip in direct contact with patient fluids where a rinsing fluid is used to spray the sensor tip, as recited in the claims.

The Savage et al. reference generally describes a catheter for use during a surgical procedure where a patient receives laser irradiation treatment for conditions affecting the cardiovascular system. As such, use of the Savage et al. catheter is limited to the amount of time the patient actually spends in the surgery room receiving the laser irradiation treatment, not for implantable use. Specifically, the Savage et al. reference describes a multi-fiber laser irradiation catheter including a flush port 29, which defines an axially-disposed lumen forming a "conduit for conducting flushing/cooling fluid through the catheter and to the site of irradiation" (col. 7, lines 15-16). The Savage et al. reference does not, however, disclose, teach or suggest an implantable sensor as recited in the amended claims. The Examiner incorrectly concludes that the Savage et al. reference shows an "implantable sensor system for taking readings from a patient including implantable sensors 52 and 54" (see page 2 of the Office Action). Sensors 52 and 54 are not implantable sensors in any form. They are only used during the laser irradiation process to "dynamically monitor and control the tissue irradiation process" (col. 4, lines 13-14) and "provide an indication of the temperature of the tissue being treated" (col. 2, line 67). Since sensors 52 and 54 are not implanted in the body of the patient, the Savage et al. reference does not anticipate the claimed subject matter, as amended.

Furthermore, the Savage et al. reference does not disclose, teach or suggest an implantable sensor having a proximal end to anchor the implantable sensor within the patient, as recited in the amended claims. Although the sensors 52 and 54 of the Savage et al. reference are inserted into the patient during laser irradiation treatment, neither the catheter assembly nor the sensors themselves are anchored within the patient. Applicants' specification describes the implantation of the sensor unit 16 within the body of the patient (¶ [0017]) where the distal end of the implantable sensor is in direct contact with patient fluids and the proximal end of the implantable sensor is anchored within the patient. Since the proximal end of the Savage et al. catheter is never fully inserted into the body of the patient, the proximal end can never be

anchored within the patient, as recited in the amended claims. Therefore, the Savage et al. reference does not anticipate the claimed subject matter, as amended.

The Savage et al. reference does not disclose, teach or suggest an implantable sensor having a distal end with a sensor tip for direct contact with patient fluids, as recited in the amended claims. Sensors 52 and 54 of the Savage et al. reference are not used for direct contact with patient fluids; rather, they are used to monitor tissue temperature at the sight of irradiation during the irradiation process. The presence of fluids at the placement site is precisely why the Savage et al. reference uses flushing/cooling fluid—to remove body fluid from the placement site to gain appropriate temperature readings during the irradiation process. Applicants' specification, on the other hand, describes the use of enzymatic sensors for measuring fluid conductivity changes in response to enzymatic reactions where patient fluids are an essential element. As explained in applicants' specification, "[t]he implantable sensor is primarily adapted for use with blood" (¶ [0012]). Accordingly, since the specified purpose of the Savage et al. reference is to remove blood from the field of view during the irradiation process (col. 4, line 46; col. 9., line 1; and col. 11, lines 14-15), the Savage et al. reference effectively teaches away from the claimed subject matter, as amended.

Additionally, the Savage et al. reference does not disclose, teach or suggest an implantable sensor system where a rinsing fluid is used to spray the sensor tip, as recited in the amended claims. The Examiner has incorrectly concluded that the Savage et al. reference "shows . . . a flush sleeve 22 for directing flushing fluid to the tip" (see page 2 of the Office Action). The flushing/cooling liquid of the Savage et al. reference is used for clearing away fluid, i.e. blood (col. 9, line 1), from the treatment site and cooling tissue at the placement site to gain appropriate temperature readings of the tissue during the laser irradiation process. The flushing/cooling liquid of the Savage et al. reference is not used to spray the sensor tip, as recited in the claims. The reference specifically explains that "this [flushing/cooling] liquid cools both the instrument and tissue and further cools the tissue and removes blood from the field of view of the laser energy during the irradiation process" (col. 4, lines 43-48). Contrastingly, the purpose of the flush sleeve in the present application is to remove proteins, fats and other clotting agents that tend to develop on the sensor tip due to its prolonged direct contact with patient fluids—

especially blood. The cleaning feature provided by the flush sleeve and spraying mechanism of the application enhances the effectiveness of the sensor by spraying the sensor tip—not spraying the placement site as described in the Savage et al. reference. Additionally, with the passage of time, this cleaning feature allows the sensor to continuously and/or intermittently monitor body fluid levels, i.e. blood glucose levels, and remain implanted and anchored in the body of a patient for a substantial period of time. Since the Savage et al. reference uses a flushing/cooling liquid to clear away fluid from the placement site, not for spraying the sensor tip, the Savage et al. reference does not anticipate the claimed subject matter, as amended.

The dependent claims 2, 4, 6-8, and 22 are further distinguished by virtue of depending on independent claims 1 and 21 and reciting additional features not provided for in the Savage et al. reference.

Therefore, it is respectfully submitted that the rejection of claims 1, 2, 4, 6-8, 21, and 22 under 35 U.S.C. § 102(b) should be withdrawn.

Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage et al. (U.S. Patent No. 5,830,209) in view of Odell et al. (U.S. Patent App. No. 2003/012025). This rejection is respectfully traversed.

Claim 3 depends from independent claim 1, which was patentably distinguished from the Savage et al. reference as discussed above. Accordingly, claim 3 is further distinguished over the Savage et al. reference.

The Odell et al. reference describes a syringe assembly for use in an IV flush procedure. However, The Odell et al. reference does not make up the deficiencies of the Savage et al. reference. The Odell et al. reference was cited by the Examiner for teaching a known method of delivering a flushing solution by piercing a septum with a needle to deliver the fluid (see page 3 of the Office Action). The combination of the Odell et al. and Savage et al. references do not disclose, teach, suggest or otherwise render obvious the claimed subject matter because the Odell et al. reference does not disclose, teach or suggest an implantable sensor system comprising an

implantable sensor having a distal end with a sensor tip for direct contact with patient fluids and a proximal end to anchor the implantable sensor within the patient; a flush sleeve directed towards the sensor tip; a rinsing fluid; and a fluid conduit in fluid communication with the flush sleeve; wherein the rinsing fluid received in the fluid conduit is used to spray the sensor tip, and wherein the flush sleeve concentrically surrounds the implantable sensor around a substantially common axis, such that the sensor is within the flush sleeve.

Further, the Odell reference does not disclose, teach, suggest or otherwise render obvious an implantable sensor system including a septum and a protector sleeve as recited in amended claim 3. Claim 3 now recites "[t]he implantable sensor system of claim 1, wherein the fluid conduit contains a septum and a protector sleeve, wherein the septum is pierced by a needle injected into the patient to deliver the rinsing fluid into the fluid conduit, and wherein the protector sleeve acts as a backstop to prevent the needle from penetrating the sensor" (emphasis added). The Odell et al. reference shows an IV set 48, which houses a septum 53 (FIG. 2, ¶ [0025]-[0026]). However, the IV set 48 is located outside the body of the patient. Nowhere in the cited sections of the Odell et al. reference teaches, discloses, or suggests a method of refilling an implanted fluid conduit. Since the IV set 48 of the Odell et al. reference can be visibly guided when filling, a protector sleeve is not needed. In contrast, the septum of the claimed subject matter is implanted within the body of the patient, as shown in FIGS. 1 and 2 of Applicants' specification. Therefore, a protector sleeve 25 is important to act as a backstop to prevent a needle from penetrating the sensor. Since the Odell et al. reference does not show an implantable sensor system that includes a septum and a protector sleeve, it does not render amended claim 3 obvious.

Therefore, it is respectfully submitted that the rejection of claim 3 under 35 U.S.C. § 103(a) should be withdrawn.

Claims 5 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage et al. (U.S. Patent No. 5,830,209) in view of Masterson et al. (U.S. Patent No. 5,891,094). This rejection is respectfully traversed.

Claims 5 and 23 depend from independent claims 1 and 21, respectively, which were patentably distinguished from the Savage et al. reference as discussed above. Accordingly, claims 5 and 23 are also distinguished over the Savage et al. reference.

The Masterson et al. reference does not make up the deficiencies of the Savage et al. reference. The Masterson et al. reference was cited by the Examiner for showing a one-way valve in the flush line to prevent backwash for the flushing solution (see page 3 of the Office Action). The combination of the Masterson et al. and Savage et al. references do not disclose, teach, suggest or otherwise render obvious the claimed subject matter because the Masterson et al. reference does not disclose, teach or suggest an implantable sensor system comprising an implantable sensor having a distal end with a sensor tip for direct contact with patient fluids and a proximal end to anchor the implantable sensor within the patient; a rinsing fluid; and a fluid conduit in fluid communication with the flush sleeve; wherein the rinsing fluid received in the fluid conduit is used to spray the sensor tip, and wherein the flush sleeve concentrically surrounds the implantable sensor around a substantially common axis, such that the sensor is within the flush sleeve.

Therefore, it is respectfully submitted that the rejection of claims 5 and 23 under 35 U.S.C. § 103(a) should be withdrawn.

Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage et al. (U.S. Patent No. 5,830,209) in view of Newman et al. (U.S. Patent No. 6,358,244). This rejection is respectfully traversed.

Claim 9 depends from independent claim 1, which was patentably distinguished from the Savage et al. reference as discussed above. Accordingly, claim 9 is also distinguished over the Savage et al. reference.

The Newman et al. reference does not make up the deficiencies of the Savage et al. reference. The Newman et al. reference was cited by the Examiner for teaching that saline is a known flush solution (see page 3 of the Office Action). The combination of the Newman et al.

and Savage et al. references do not disclose, teach, suggest or otherwise render obvious the claimed subject matter because the Newman et al. reference does not disclose, teach or suggest an implantable sensor system comprising an implantable sensor having a distal end with a sensor tip for direct contact with patient fluids and a proximal end to anchor the implantable sensor within the patient; a flush sleeve directed towards the sensor tip; a rinsing fluid; and a fluid conduit in fluid communication with the flush sleeve; wherein the rinsing fluid received in the fluid conduit is used to spray the sensor tip, and wherein the flush sleeve concentrically surrounds the implantable sensor around a substantially common axis, such that the sensor is within the flush sleeve.

Therefore, it is respectfully submitted that the rejection of claim 9 under 35 U.S.C. § 103(a) should be withdrawn.

Claim 10 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage et al. (U.S. Patent No. 5,830,209) in view of Riccitelli et al. (U.S. Patent No. 5,166,990). This rejection is respectfully traversed.

Claim 10 depends from independent claim 1, which was patentably distinguished from the Savage et al. reference as discussed above. Accordingly, claim 10 is also distinguished over the Savage et al. reference.

The Riccitelli et al. reference does not make up the deficiencies of the Savage et al. reference. The Riccitelli et al. reference was cited by the Examiner for teaching that heparin is a known flush solution (see page 3 of the Office Action). The combination of the Riccitelli et al. and Savage et al. references do not disclose, teach, suggest or otherwise render obvious the claimed subject matter because the Riccitelli et al. reference does not disclose, teach or suggest an implantable sensor system comprising an implantable sensor having a distal end with a sensor tip for direct contact with patient fluids and a proximal end to anchor the implantable sensor within the patient; a flush sleeve directed towards the sensor tip; a rinsing fluid; and a fluid conduit in fluid communication with the flush sleeve; wherein the rinsing fluid received in the fluid conduit is used to spray the sensor tip, and wherein the flush sleeve concentrically

surrounds the implantable sensor around a substantially common axis, such that the sensor is within the flush sleeve.

Therefore, it is respectfully submitted that the rejection of claim 10 under 35 U.S.C. § 103(a) should be withdrawn.

Claim 11 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Savage et al. (U.S. Patent No. 5,830,209) in view of Wulfman et al. (U.S. Patent Application No. 2002/0007190). This rejection is respectfully traversed.

Claim 11 depends from independent claim 1, which was patentably distinguished from the Savage et al. reference as discussed above. Accordingly, claim 11 is also distinguished over the Savage et al. reference.

The Wulfman et al. reference does not make up the deficiencies of the Savage et al. reference. The Wulfman et al. reference was cited by the Examiner for teaching the equivalence of wireless or wired connections between implanted temperature sensors and the monitor (see page 4 of the Office Action). The combination of the Wulfman et al. and Savage et al. references do not disclose, teach, suggest or otherwise render obvious the claimed subject matter because the Wulfman et al. reference does not disclose, teach or suggest an implantable sensor system comprising an implantable sensor having a distal end with a sensor tip for direct contact with patient fluids and a proximal end to anchor the implantable sensor within the patient; a flush sleeve directed towards the sensor tip; a rinsing fluid; and a fluid conduit in fluid communication with the flush sleeve; wherein the rinsing fluid received in the fluid conduit is used to spray the sensor tip, and wherein the flush sleeve concentrically surrounds the implantable sensor around a substantially common axis, such that the sensor is within the flush sleeve.

Therefore, it is respectfully submitted that the rejection of claim 11 under 35 U.S.C. § 103(a) should be withdrawn.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Examination and consideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned attorney at (818) 576-5003 should the Examiner believe a telephone interview would advance the prosecution of the application.

Respectfully submitted,

Dated: 3/14/05

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